

UpCard

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued/ amended on	Product Information affected ²	Summary ³
R/0004	Renewal of the marketing authorisation.	23/04/2020	24/06/2020	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for UpCard.
IA/0003	A.7 - Administrative change - Deletion of manufacturing sites	04/04/2019	n/a		n/a
IG/0842	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	21/09/2017	n/a		n/a
IA/0001	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	02/05/2017	n/a		n/a

¹ Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.

² SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

³ Since October 2019 summary information is no longer published for variations that do not impact upon the product information